Attorney's Docket No.: 16614-030001 / 0054.13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Thomas E. Tarara et al.	Art Unit	: 1616
Serial No.	: 10/612,393	Examiner	: Sharmila S. Gollamudi
Filed	: July 3, 2003		
Title	: ENGINEERED PARTICLES AND METHODS OF USE		

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

This filing is being made with the filing of a Request for Continued Examination. No fee is required.

Respectfully submitted,

Date: May 9, 2006

Jennifer A. Zanocco
Reg. No. 54,563

Customer No. 26181
Fish & Richardson P.C.
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

50345828.doc

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A1	2002/0127188	09/2002	Platz et al.			
	A2	2002/0132787	09/2002	Eljamal et al.			
	A3	2002/0192164	12/2002	Patton et al.			
	A4	2003/0035778	02/2003	Platz et al.			
	A5	2003/0068279	04/2003	Platz et al.			
	A6	2003/0072718	04/2003	Platz et al.			
	A7	2003/0086877	05/2003	Platz et. al.			
	A8	2003/0092666	05/2003	Eljamal et al.			
	A9	2003/0113273	06/2003	Patton et al.			
	A10	2003/0113900	06/2003	Tunnacliffe et al.			
	A11	2003/0171282	09/2003	Patton			
	A12	2003/0185765	10/2003	Platz et al.			
	A13	2003/0198601	10/2003	Platz et al.			
	A14	2003/0203036	10/2003	Gordon et al.			
	A15	2003/0215512	11/2003	Foster et al.			
	A16	2003/0215514	11/2003	Platz et al.			
	A17	2004/0052825	03/2004	Roser et al.			
	A18	2004/0096400	05/2004	Patton et al.			
	A19	2004/0096401	05/2004	Patton et al.			
	A20	2004/0219206	11/2004	Roser et al.			
	A21	2005/0147566	07/2005	Fleming et al.			
	A22	2005/0186143	08/2005	Stevenson et al.			
	A23	2005/0203002	09/2005	Tzannis et al.			
	A24	979993	12/1910	O'Byrne et al.			
	A25	1855591	04/1932	Wallerstein			
	A26	2457036	12/1948	Epstein			
	A27	3362405	01/1968	Hazel			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A28	3555717	01/1971	Chivers			
	A29	3619294	11/1971	Black et al			
	A30	3632357	01/1972	Childs			
	A31	3655442	04/1972	Schwer et al.			
	A32	3745682	07/1973	Waldeisen			
	A33	3948263	04/1976	Drake, Jr. et al.			
	A34	3964483	06/1976	Mathes			
	A35	4036223	07/1977	Obert			
	A36	4098273	07/1978	Glenn			
	A37	4102999	07/1978	Umezawa et al.			
	A38	4127502	11/1978	Li Mutti et al.			
	A39	4158544	06/1979	Louderback			
	A40	4159319	06/1979	Bachmann et al.			
	A41	4211769	07/1980	Okada et al.			
	A42	4244949	01/1981	Gupta			
	A43	4153468	03/1981	Lehmbeck			
	A44	4326524	04/1982	Drake, Jr. et al.			
	A45	4327076	04/1982	Puglia et al.			
	A46	4327077	04/1982	Puglia et al.			
	A47	4371557	02/1983	Oppy et al.			
	A48	4407786	10/1983	Drake et al.			
	A49	4452239	06/1984	Malem			
	A50	4484577	11/1984	Sackner et al.			
	A51	4534343	08/1985	Nowacki et al.			
	A52	4588744	05/1986	McHugh			
	A53	4591552	05/1986	Neurath			
	A54	4613500	09/1985	Suzuki et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A55	4617272	10/1986	Kirkwood et al.			
	A56	4620847	11/1986	Shishov et al.			
	A57	4659696	04/1987	Hirai et al.			
	A58	4680027	07/1987	Parsons et al.			
	A59	4684719	08/1987	Nishikawa et al.			
	A60	4701417	10/1987	Portenhauser et al.			
	A61	4713249	12/1987	Schröder			
	A62	4721709	01/1988	Seth et al.			
	A63	4739754	04/1988	Shaner			
	A64	4758583	07/1988	Cerami et al.			
	A65	4761400	08/1988	Doat et al.			
	A66	4762857	08/1988	Bollin, Jr. et al.			
	A67	4790824	12/1988	Morrow et al.			
	A68	4793997	12/1988	Drake et al.			
	A69	4812444	03/1989	Mitsuhashi et al.			
	A70	4814436	03/1989	Shibata et al.			
	A71	4819629	04/1989	Jonson			
	A72	4824938	04/1989	Koyama et al.			
	A73	4830858	05/1989	Payne et al.			
	A74	4847079	07/1989	Kwan			
	A75	4855326	08/1989	Fuisz			
	A76	4861627	08/1989	Mathiowitz et al.			
	A77	4865871	09/1989	Livesey et al.			
	A78	4866051	09/1989	Hunt			
	A79	4883762	11/1989	Hoskins			
	A80	4891319	01/1990	Roser			
	A81	4906463	03/1990	Cleary et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A82	4907583	03/1990	Wetterlin et al.			
	A83	4942544	07/1990	McIntosh et al.			
	A84	4984158	01/1991	Hillsman			
	A85	4988683	01/1991	Corbiere			
	A86	5006343	04/1991	Benson et al.			
	A87	5011678	04/1991	Wang et al.			
	A88	5013557	05/1991	Tai			
	A89	5017372	05/1991	Hastings			
	A90	5026566	06/1991	Roser			
	A91	5026772	06/1991	Kobayashi et al.			
	A92	5033463	07/1991	Cocozza			
	A93	5043165	08/1991	Radhakrishnan			
	A94	5049388	09/1991	Knight et al.			
	A95	5049389	09/1991	Radhakrishnan			
	A96	5089181	02/1992	Hauser			
	A97	5098893	03/1992	Franks et al.			
	A98	5112596	05/1992	Malfroy-Camine			
	A99	5112598	05/1992	Bielsalski			
	A100	5149653	09/1992	Roser			
	A101	5160745	11/1992	DeLuca, et al.			
	A102	5173298	12/1992	Meadows			
	A103	5200399	04/1993	Wettlaufer et al.			
	A104	5202333	04/1993	Berger et al.			
	A105	5204108	04/1993	Illum			
	A106	5215079	06/1993	Fine et al.			
	A107	5239993	08/1993	Evans			
	A108	5240712	08/1993	Smith et al.			

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A109	5240843	08/1993	Gibson et al.			
	A110	5240846	08/1993	Collins et al.			
	A111	5254330	10/1993	Ganderton et al.			
	A112	5270048	12/1993	Drake			
	A113	5284656	02/1994	Platz et al.			
	A114	5290765	03/1994	Wettlaufer			
	A115	5306506	04/1994	Zema et al.			
	A116	5309900	05/1994	Knoch et al.			
	A117	5312335	05/1994	McKinnon et al.			
	A118	5312909	05/1994	Driessen et al.			
	A119	5342625	08/1994	Hauer et al.			
	A120	5348852	09/1994	Bonderman			
	A121	5354562	10/1994	Platz et al.			
	A122	5354934	10/1994	Pitt et al.			
	A123	5366734	11/1994	Hutchinson			
	A124	5380473	01/1995	Bogue et la.			
	A125	5387431	02/1995	Fuisz			
	A126	5403861	04/1995	Goldwin et al.			
	A127	5404871	04/1995	Goodman et al.			
	A128	5422360	06/1995	Miyajima et al.			
	A129	5422384	06/1995	Samuels et al.			
	A130	5425951	06/1995	Goodrich, Jr. et al.			
	A131	5453514	09/1995	Niigata et al.			
	A132	5458135	10/1995	Patton et al.			
	A133	5482927	01/1996	Maniar et al.			
	A134	5512547	04/1996	Johnson et al.			
	A135	5518709	05/1996	Sutton et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A136	5547696	08/1996	Sorensen			
	A137	5567439	10/1996	Myers et. al.			
	A138	5571499	11/1996	Hafler et al.			
	A139	5580859	12/1996	Felgner et al.			
	A140	5589167	12/1996	Cleland et al.			
	A141	5591453	01/1997	Ducheyne et al.			
	A142	5607915	03/1997	Patton et al.			
	A143	5618786	04/1997	Roosdorp et al.			
	A144	5621094	04/1997	Roser et al.			
	A145	5631225	05/1997	Sorensen			
	A146	5642728	07/1997	Andersson et al.			
	A147	5654278	08/1997	Sorensen			
	A148	5681746	10/1997	Bodner et al.			
	A149	5705482	01/1998	Christensen et al.			
	A150	5707644	01/1998	Illum et al.			
	A151	5728574	03/1998	Legg			
	A152	5733555	03/1998	Chu			
	A153	5766520	06/1998	Bronshtein			
	A154	5775320	07/1998	Patton et al.			
	A155	5780014	07/1998	Eljamal et al.			
	A156	5780295	07/1998	Livesey et al.			
	A157	5849700	12/1998	Sorensen et al.			
	A158	5851453	12/1998	Hanna et al.			
	A159	5891873	04/1999	Colaco et al.			
	A160	5928469	07/1999	Franks et al.			
	A161	5948411	09/1999	Koyama et al.			
	A162	5955448	09/1999	Colaco et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A163	5972366	10/1999	Haynes et al.			
	A164	5976436	11/1999	Livesley et al.			
	A165	5993783	11/1999	Eljamal et al.			
	A166	5993805	11/1999	Sutton et al.			
	A167	5994314	11/1999	Eljamal et al.			
	A168	5997848	12/1999	Patton			
	A169	6013638	01/2000	Crystal et al.			
	A170	6019968	02/2000	Platz et al.			
	A171	6034080	03/2000	Colaco et al.			
	A172	6051256	04/2000	Platz et al.			
	A173	6060069	05/2000	Hill et al.			
	A174	6071428	06/2000	Franks et al.			
	A175	6077543	06/2000	Gordon et al.			
	A176	6123924	09/2000	Mistry et al.			
	A177	6123936	09/2000	Platz et al.			
	A178	6136346	10/2000	Eljamal et al.			
	A179	6138668	10/2000	Patton et al.			
	A180	6142216	11/2000	Lannes			
	A181	6165463	12/2000	Platz et al.			
	A182	6187344	02/2001	Elijamal et. al.			
	A183	6190859	02/2001	Putnak et al.			
	A184	6231851	05/2001	Platz et al.			
	A185	6258341	07/2001	Foster et al.			
	A186	6290991	09/2001	Roser et al.			
	A187	6303581	10/2001	Pearlman			
	A188	6303582	10/2001	Eljamel et al.			
	A189	6309671	10/2001	Foster et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A190	6313102	11/2001	Colaco et al.			
	A191	6331310	12/2001	Roser et al.			
	A192	6334182	02/2002	Sutton et al.			
	A193	6358530	03/2002	Eljamal et al.			
	A194	6365190	04/2002	Gordon et al.			
	A195	6372258	04/2002	Platz et al.			
	A196	6423334	07/2002	Brayden et al.			
	A197	6423344	07/2002	Platz et al.			
	A198	6426210	07/2002	Franks et al.			
	A199	6468782	10/2002	Tunnacliffe et al.			
	A200	6479049	11/2002	Platz et al.			
	A201	6503411	01/2003	Franks et al.			
	A202	6509006	01/2003	Platz et al.			
	A203	6514496	02/2003	Platz et al.			
	A204	6518239	02/2003	Kuo et al.			
	A205	6565871	05/2003	Roser et al.			
	A206	6569406	05/2003	Stevenson et al.			
	A207	6569458	05/2003	Gombotz et al.			
	A208	6572893	06/2003	Gordon et al.			
	A209	6582728	06/2003	Platz et al.			
	A210	6586006	07/2003	Roser et al.			
	A211	6589560	07/2003	Foster et al.			
	A212	6592904	07/2003	Platz et al.			
	A213	6630169	10/2003	Bot et al.			
	A214	6649911	11/2003	Kawato			
	A215	6655379	12/2003	Clark et al.			
	A216	6673335	01/2004	Platz et al.			

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A217	6681767	01/2004	Patton et al.			
	A218	6685967	02/2004	Patton et al.			
	A219	6737045	05/2004	Patton et al.			
	A220	6737066	05/2004	Moss			
	A221	6752893	06/2004	Frieder, Jr.			
	A222	6797258	09/2004	Platz et al.			
	A223	6811792	11/2004	Roser et al.			
	A224	6825031	11/2004	Franks et al.			
	A225	6893657	05/2005	Roser et al.			
	A226	6921527	07/2005	Platz et al.			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	B1	714998	01/2000	AU				
	B2	902257	08/1985	BE			Abstr.	
	B3	0161072	10/1904	DE				
	B4	471490	08/1931	DE			X	
	B5	1080265	04/1960	DE			X	
	B6	3141498	04/1983	DE			X	
	B7	0015123	03/1980	EP				
	B8	0072046	02/1983	EP				
	B9	0090356	10/1983	EP				
	B10	0111216	06/1984	EP				
	B11	0136030	04/1985	EP				
	B12	0139286	05/1985	EP				
	B13	0140489	05/1985	EP				
	B14	0222313	05/1987	EP				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	B15	0229810	07/1987	EP				
	B16	0257956	03/1988	EP				
	B17	0282179	09/1988	EP				
	B18	0325936	08/1989	EP				
	B19	0356154	02/1990	EP				
	B20	0360340	03/1990	EP				
	B21	0366303	05/1990	EP				
	B22	0383569	08/1990	EP				
	B23	0415567	03/1991	EP				
	B24	0430045	06/1991	EP				
	B25	0433679	06/1991	EP				
	B26	0463653	01/1992	EP				
	B27	0474874	03/1992	EP				
	B28	0520748	12/1992	EP				
	B29	0600730	0/1994	EP				
	B30	0616524	09/1994	EP				
	B31	0714905	06/1996	EP				
	B32	84-03520	06/1984	ES			Abstr.	
	B33	2238476	02/1975	FR			Abstr.	
	B34	1288094	09/1972	GB				
	B35	1381588	01/1975	GB				
	B36	1477775	06/1977	GB				
	B37	1533012	11/1978	GB				
	B38	2126588	03/1984	GB				
	B39	21878191	01/1987	GB				
	B40	52-139789	11/1977	JP			Abstr.	
	B41	58-216695	12/1983	JP			Abstr.	

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	B42	59-095885	06/1984	JP			Abstr.	
	B43	60-244288	12/1985	JP			Abstr.	
	B44	62-228272	10/1987	JP			Abstr.	
	B45	62-255434	11/1987	JP			Abstr.	
	B46	03-038592	02/1991	JP			Abstr.	
	B47	06-100464	04/1994	JP			Abstr.	
	B48	86/04095	07/1986	WO				
	B49	87/00196	01/1987	WO				
	B50	87/02038	04/1987	WO				
	B51	87/05300	09/1987	WO				
	B52	88/08298	11/1988	WO				
	B53	89/06976	08/1989	WO				
	B54	90/05182	05/1990	WO				
	B55	90/15635	12/1990	WO				
	B56	90/11756	10/1990	WO				
	B57	91/06282	05/1991	WO				
	B58	91/16038	10/1991	WO				
	B59	91/16882	11/1991	WO				
	B60	91/18091	11/1991	WO				
	B61	92/02133	02/1992	WO				
	B62	92/19243	11/1992	WO				
	B63	93/00951	01/1993	WO				
	B64	93/02834	02/1993	WO				
	B65	93/09832	05/1993	WO				
	B66	93/10758	06/1993	WO				
	B67	93/11746	06/1993	WO				
	B68	93/12240	06/1993	WO				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	B69	93/13752	07/1993	WO				
	B70	93/17663	09/1993	WO				
	B71	93/23065	11/1993	WO				
	B72	93/23110	11/1993	WO				
	B73	94/07514	04/1994	WO				
	B74	94/13271	06/1994	WO				
	B75	94/22423	10/1994	WO				
	B76	94/24263	10/1994	WO				
	B77	95/00127	01/1995	WO				
	B78	95/01324	01/1995	WO				
	B79	95/06126	03/1995	WO				
	B80	95/20979	08/1995	WO				
	B81	95/24183	09/1995	WO				
	B82	95/31479	11/1995	WO				
	B83	95/33488	12/1995	WO				
	B84	96/03978	02/1996	WO				
	B85	96/09085	03/1996	WO				
	B86	96/27393	09/1996	WO				
	B87	96/32096	10/1996	WO				
	B88	96/40049	12/1996	WO				
	B89	96/40077	12/1996	WO				
	B90	97/26863	07/1997	WO			Abstr.	
	B91	97/34689	09/1997	WO				
	B92	98/24882	06/1998	WO				
	B93	98/58989	12/1998	WO				
	B94	01/87278	11/2001	WO				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Attorney's Docket No.: 16614-030001 / 0054.13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Thomas E. Tarara et al.	Art Unit	: 1616
Serial No.	: 10/612,393	Examiner	: Sharmila S. Gollamudi
Filed	: July 3, 2003		
Title	: ENGINEERED PARTICLES AND METHODS OF USE		

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT IN REPLY TO ACTION OF FEBRUARY 9, 2006

Please amend the above-identified application as follows:

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (canceled)

2. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.1 g/cm^3.

3. (withdrawn) The composition according to claim 2, wherein the mean geometric particle size of said microspheres is less than 20 μm.

4. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 43.5 to 261 nm.

5. (withdrawn) The composition according to claim 2 wherein the walls of said microspheres comprise albumin.

6. (withdrawn) The composition according to claim 2 obtainable by spray-drying a wall-forming material in combination with a blowing agent.

7. (withdrawn) The composition according to claim 2 wherein said microspheres comprise a bioactive agent.

8. (withdrawn) The composition according to claim 7, wherein said microspheres comprise a protein or peptide.

9. (withdrawn) The composition according to claim 7, wherein said microspheres comprise an active agent selected from the group consisting of insulin, growth hormone and interferon.

10. (withdrawn) An inhaler comprising an inhalable formulation of microspheres wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.1 g/cm^3 and wherein said microspheres comprise a bioactive agent.

11. (withdrawn) The inhaler according to claim 10, wherein the formulation comprises the microspheres as the sole or the predominant component thereof.

12. (withdrawn) A method for pulmonary administration of a bioactive agent wherein said method comprises the administration to the lungs of a composition which comprises microspheres having a wall thickness of 100 to 500 nm and a bulk density of no more than 0.1 g/cm^3, wherein said microspheres further comprise a bioactive agent.

13. (withdrawn) The method according to claim 12, wherein the mean geometric diameter of said microspheres is less than 20 μm.

14. (withdrawn) A method for pulmonary administration of a bioactive agent wherein said method comprises the administration to the lungs of a composition which comprises microspheres having a wall thickness of 43.5 to 261 nm and a bulk density of no more than 0.1 g/cm^3, wherein said microspheres further comprise a bioactive agent.

15. (withdrawn) The method according to claim 12, wherein the walls of said microspheres comprise albumin.

16. (withdrawn) The method according to claim 12, wherein said microspheres are obtainable by spray-drying a wall-forming material, in combination with a blowing agent.

17. (withdrawn) The method according to claim 12, wherein said microspheres comprise a

protein or peptide.

18. (withdrawn) The method according to claim 12, wherein said microspheres contain a bioactive agent selected from the group consisting of insulin, growth hormone and interferon.

19. (withdrawn) A method for diagnosis wherein said method comprises administering to a patient in need of such diagnosis, a composition which comprises microspheres having a wall thickness of 100 to 500 nm and a bulk density of no more than 0.1 g/cm^3.

20. (withdrawn) The method according to claim 19, wherein the mean geometric diameter of said microspheres is less than 20 μm.

21. (withdrawn) A method for diagnosis wherein said method comprises administering to a patient in need of such diagnosis, a composition which comprises microspheres having a wall thickness of 43.5 to 261 nm and a bulk density of no more than 0.1 g/cm^3.

22. (withdrawn) The method according to claim 19, wherein the walls of said microspheres comprise albumin.

23. (withdrawn) The method according to claim 19, wherein said microspheres are obtainable by spray-drying a wall-forming material, in combination with a blowing agent.

24. (currently amended) A method for preparing microparticles, wherein said method comprises spray-drying wall-forming materials to form said microparticles, wherein said microparticles have a wall thickness of about 100 to 500 nanometers, said ~~wall-foming~~ wall-forming materials include a therapeutic bioactive agent and said method further comprises inclusion of a blowing agent in the feedstock for spray-drying.

25. (previously presented) The method according to claim 24, wherein said blowing agent is selected from the group consisting of ammonium acetate and ammonium carbonate.

26. (previously presented) The method according to claim 24, wherein said wall-forming material is albumin.

27. (withdrawn) A composition comprising microspheres, wherein said microspheres have a wall thickness of 100 to 500 nm, and a bulk density of no more than 0.3 g/cm^3.

28. (withdrawn) The composition according to claim 2 wherein the bulk density is no more than 0.05 g/cm^3.

REMARKS

Claim Amendments

Claim 24 has been amended to correct a typographical error.

Information Disclosure Statement

Some of the references in the Information Disclosure Statement of November 9, 2005, were not considered. The applicant submits herewith an Information Disclosure Statement with the references that were previously not submitted along with additional references. The applicant requests that the Examiner review the submitted references, initial the PTO-1449 and return the initially PTO-1449 to the applicant.

Rejections Under Section 103

Claims 24 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 92/18164 ("Sutton") in view of WO 96/15814 ("Osborne"). The applicant respectfully traverses.

Claim 24 is directed to a method for preparing microparticles. The method comprises spray-drying wall-forming materials. The wall-forming materials include a therapeutic bioactive agent. The method further comprises inclusion of a blowing agent in the feedstock for spray-drying. Claim 26 depends from claim 24.

Sutton describes preparing microcapsules from albumin (Abstract). The microcapsules are injected into a patient and are allowed to flow through the heart, lungs and veins (page 18, lines 13-20). Ultrasonic scanning equipment is used to image the microcapsules in the body to show unusual blood flow within the heart, valvular competence, chamber size, wall motion and indications of myocardial perfusion (page 17, line 21-page 19, line 11). As noted by the Examiner, Sutton does not teach a blowing agent or a bioactive agent as an additive in a spray drying solution.

Osborne describes a process for forming microcapsules from albumin for ultrasound echogenic contrast agents (Abstract). Osborne also fails to teach using a bioactive agent.

Both Sutton and Osborne fail to suggest or disclose therapeutic agents or spray-drying wall-forming materials including a therapeutic bioactive agent therapeutic bioactive agent to form a microparticle. Applicant agrees with the Examiner that "Sutton does not specify the use of a blowing agent or a bioactive agent as the additive in the spray drying solution" (Office Action page 4). However, the applicant does not agree with the Examiner's rejection based on the teachings of Sutton. The Examiner argues that "One would have been motivated to add a bioactive agent such as a contrast agent or a magnetic resonance imaging agent to the spray solution. A skilled artisan would have been motivated to do so since Sutton teaches the microcapsules are utilized for imaging areas in the body and the inclusion of a contrast agent or a magnetic resonance imaging agent would further enhance the imaging process" (Office action, pages 5-6). The applicant respectfully disagrees with the Examiner's interpretation of a contrast agent or a magnetic resonance imaging agent as a bioactive agent. While these agents enable a scanner to image the agent within the body, these agents are not necessarily bioactive. Further, the Examiner has ignored the adjective "therapeutic", as required by claim 24. A contrast agent or a magnetic resonance imaging agent is not intended to be therapeutic, but is rather used to help diagnose or monitor a patient's condition. Thus, both Sutton and Osborne fail to suggest using a therapeutic bioactive agent. Moreover, nothing in Sutton or Osborne would motivate one to add a therapeutic bioactive agent to the microcapsules of either Sutton or Osborne or a combination thereof. Thus, applicant submits that no *prima facie* case of obviousness has been made with respect to claims 24 and 26.

In addition, claim 39 of U.S. Patent No. 6,416,739 ("Rogerson") recites a method for preparing microparticles, wherein the method comprises spray-drying wall-forming materials and inclusion of a blowing agent in the feedstock for spray-drying. Claim 39 includes some of the limitations of applicant's claim 24. According to the Examiner's arguments, Sutton and Osborne could have been used to reject Rogerson's claim 39. Accordingly, the office action including the rejection of applicant's claims should have been signed by the TC Director (See MPEP § 1003).

Claim 25 is rejected as being unpatentable over Sutton in view of Osborne in view of U.S. Patent No. 2,797,201 ("Veatch"). The applicant respectfully disagrees.

Claim 25 depends from claim 24 and necessarily includes the limitations of claim 24.

Veatch describes making hollow particles for low density products, such as linoleum and floor tile, as aggregate in concrete and plaster, plastic foam, gaskets, seals, buoys, flotation equipment, boat hulls and other items (col. 10, lines 27-49).

Veatch does not suggest or disclose a therapeutic bioactive agent. Because each of Sutton, Osborne and Veatch fail to suggest or disclose spray-drying wall-forming materials including a therapeutic bioactive agent therapeutic bioactive agent to form a microparticle, applicant respectfully submits that no *prima facie* case of obviousness has been made for claim 25.

Moreover, Veatch could have been used to reject claim 39 of Rogerson. Veatch describes forming particles with sizes of about 25-250 microns, out of film forming material and a blowing agent (col. 2, lines 21-41, col. 3, lines 4-29, col. 4, lines 65-67). Spray drying is used to form the particles (col. 4, lines 4-7). Because Veatch could have been used to reject claim 39 in Rogerson, the office action including the rejection should have been signed by the TC Director (See MPEP § 1003).

Claims 24 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 3,957,964 ("Grimm") in view of U.S. Patent No. 4,180,593 ("Cohan") or vice-versa. The applicant respectfully disagrees.

Grimm describes forming dentifrice, or toothpaste, having encapsulating shells or coatings therein (Abstract). The encapsulating material can be a synthetic organic polymeric plastic (col. 3, lines 38-41). Materials that might be unstable when distributed throughout the dentrifice, such as fluorides, antibiotics, bactericides and colorants, are encapsulated for release when a user brushes with the dentifrice (col. 2, lines 9-13 and 68 and col. 3, lines 1-28). When chemical interactions with the material are to be avoided, the encapsulation provides a barrier between the encapsulated material and the dentrifrice matrix (col. 3, lines 1-27).

Cohan describes forming blown beads which comprise an edible film forming food material (col. 2, lines 14-18).

Both Grimm and Cohan fail to teach or suggest spray-drying wall-forming materials that include a therapeutic bioactive agent. Grimm suggests forming capsules that have antibiotics surrounded by a wall of polymeric plastic. Grimm encapsulates a nucleus of antibiotics, or other unstable substance, to keep the material from being exposed to the surrounding environment. To

put the antibiotics in the coating would be counter to Grimm's purpose. A modification that is counter to the purpose of a prior art reference does not provide adequate motivation for an obviousness rejection (MPEP § 2143.01V "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Cohan is silent regarding a therapeutic bioactive agent. For at least these reasons, the applicant submits that no *prima facie* case of obviousness has been made with respect to claims 24 and 25.

Moreover, according to the Examiner's arguments, Grimm and Cohan could have been used to reject claim 39 of Rogerson. Because the Examiner used Grimm and Cohan to reject applicant's claim 24, the Examiner would have similarly rejected claim 39 in Rogerson. Thus, the office action including the rejection should have been signed by the TC Director (See MPEP § 1003).

Applicant respectfully requests that the obviousness rejections be withdrawn.

Double Patenting Rejection

Claims 24-26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of U.S. Patent No. 6,565,885. Applicant respectfully requests that the Examiner hold this rejection in abeyance until the claims are determined otherwise to be allowable.

Please apply the one-month extension of time fee in the amount of 120.00 and any other required charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: May 9, 2006

Jennifer A. Zanocco
Reg. No. 54,363

Customer No. 26181
Fish & Richardson P.C.
Telephone: (650) 839-5070
Facsimile: (650) 839-5071
50329562.doc

Substitute Form PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Applicant Thomas E. Tarara et al.	
	Filing Date July 3, 2003	Group Art Unit 1616

Examiner Initial	Desig. ID	Document
	C1	Advertisement for "Stop'n Grow" Manufactured by The Mentholatum Co. Ltd., East Kilbride Scotland G74 5P3
	C2	Agrimi, U. et al., "Amyloid, Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", *Med. Hypotheses* 40(2): 113-116 (1993)
	C3	Ahlneck et al., "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State", Int's J. Pharm. 62: 87-95 (1990)
	C4	Akers, M. J. et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", *Pharmaceutical Research* 12(10):1457-1461 (1995)
	C5	Akoh et al., "One-stage synthesis of raffinose fatty acid polyesters", *J. Food Sci.* 52:1570-1576 (1987)
	C6	Alberts, B. et al., Molecular Biology of the Cell, 2nd ed., Garland Publishing, Inc., Ch. 2, page 58, (1989)
	C7	Aldous et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", *Cryo-Letters* 16:181-186 (1995)
	C8	Allen, D. J. et al., "Determination of the Degree of Crystallinity in Solid-Solid Equilibria," *J. Pharm. Sci.* 58:1190-1193 (1969)
	C9	Allison, S. D. et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", *Journal of Pharmaceutical Sciences* 89(5): 682-691 (2000)
	C10	Allison, S. D. & Anchordoquy, Thomas J., *Lyophilization of Nonviral Gene Delivery Systems*, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY, Ch. 18, 225-252 (Mark A. Findeis ed., Humana Press, 2001)
	C11	Altenbach et al., "Ca2+ Binding to Phosphatidycholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formulation of a Ca2+ Complex with Two Phosholipid Molecules" *Biochem.* 23:3913-3920 (1984)
	C12	Anchordoquy, Thomas J. et al., Physical Stabilization of DNA Based Therapeutics, 6(9) DDT 463-470 (May 2001)
	C13	Anekwe, J. et al., "Relaxation Constants as a Predictor of Protein Stabilization," *Biocalorimetry: Applications of Calorimetry in the Biological Science*, J. E. Ladbury and B. Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251 (1998)
	C14	Babincova et al., "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposimes: Possible Implications for Exocytosis", *Physiol. Res.*, 48(4):319-321 (1999)
	C15	"Drug Absorption and Availability", Modern Pharmaceutics, 3rd edition, G. S. Banker et al. (eds), Marcel Dekker, Inc., pg. 145 (1996)
	C16	Bandara, G. et al., "Interarticular Expression of Biologically Active Interleukin 1-Receptor-Antagonist Protein by Ex Vivo Gene Transfer," *Proc. Natl. Acad. Sci.* 90:10764-10768 (November 1993)
	C17	Barnett, A. H. "Exhubera Inhaled Insulin: A Review", *Int. J. Clin. Pract.* 58(4): 394-401 (2004)
	C18	Bell, J. H. et al., "Dry Powder Aerosols I: A New Powder Inhalation Device," J. Pharm. Sci. 60(10): 1559-1564 (October 1971)
	C19	Belopol'skaya, T. V. et al., The Effect of Water as Natural Plasticizer on Thermal Properties of Denaturated DNA Studied by Calorimetry 4 VESTNIK SANKT-PETERSBURGSKOGO UNIVERSITETA SERIYA pp. 16-22, abstract only, 2 pgs. (1999)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C20	Bigsbee et al., "Solid State Liability of Insulin: Comparison of Crystalline and Amorphous Forms," *Pharmaceutical Research* 10(10): Abstract No. PDD 7418, page S-279 (1993)
	C21	Blakeley et al., "Dry instant blood typing plate for bedside use," *Lancet*, 336: 854-855 (1990)
	C22	Bögelein, J. et al., "Influence of Amorphous Mannitol on Powder Properties of Spray Dried Trehalose/Dextran Mixtures", [on-line] [retrieved September 2005] Retrieved from the Internet <URL: http://www.pharmtech.unierlangen.de/APV 03 abs/bogelein.pdf > 2 pages (2003)
	C23	Bootsma, H.P.R. et al., "β-Cyclodextrin as an Excipient in Solid Oral Dosage Forms: In Vitro and In Vivo Evaluation of Spray-Dried Diazepan-β-Cyclodextrin Products," *International Journal of Pharmaceutics* 51:213-223 (1989)
	C24	Bosquillon, C. et al., "Aerosolization Properties, Surface Composition and Physical State of Spray-Dried Protein Powders", *Journal of Controlled Release* 99:357-367 (2004)
	C25	Branca, C. et al., "Destructuring effect of trehalose on the tetrahedral network of water: a Raman and neutron diffraction comparison", Physica A 304:314-318 (2002)
	C26	Branchu, S. et al. "The Effect of Cyclodextrins on Monomeric Protein Unfolding", *Biocalorimetry: Applications of Calorimetry in the Biological Science*, J. E. Ladbury and B.Z. Chowdhry (eds.), John Wiley &Sons, Ltd., 297-301 (1998)
	C27	Branchu, S. et al., "Hydroxypropyl-β-Cyclodextrin Inhibits Spray-Drying-Induced Inactivation of (β-Galactosidase", *Journal of Pharmaceutical Sciences* 88(9): 905-911 (1999)
	C28	Brange et al., "Chemical Stability of Insulin. I. Hydrolytic Degradation During Storage of Pharmaceutical Preparations," *Pharmaceutical Research* 9(6): 715-726 (1992)
	C29	Breitenbach, J. "Melt Extrusion: From Process to Drug Delivery Technology", *European Journal of Pharmaceutics and Biopharmaceutics* 54:107-117 (2002)
	C30	Broadhead, J. et al., "The Effect of Process and Formulation Variable on the Properties of Spray-Dried β-Galactosidase," *J. Pharm. Pharmacol.* 46(6):458-567 (June 1994)
	C31	Broadhead, J. et al., *The Spray Drying of Pharmaceuticals*, 18 Drug Development and Industrial Pharmacy 1169-1206 (1992)
	C32	Brown, "A Therapeutic Panorama of the Spongiform Encephalopathies", Antiviral Chem. Chemother. 1(2): 75-83 (1990)
	C33	Buckton et al., "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders", *Int. J. of Pharm.*, 123:265-271 (1995)
	C34	Buitink, Julia et al., *High Critical Temperature above Tg May Contribute to the Stability of Biological Systems* 79 BIOPHYSICAL JOURNAL 1119-1128 (August 2000)
	C35	Buldt et al., "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes", *J. Mol. Biol.* 123:673-691 (1979)
	C36	Burvall et al., "Storage of Lactose-Hydrolised Dried Milk: Effect of Water Activity on the Protein Nutritional Value", *Journal of Dairy Research* 45: 381-389 (1978)
	C37	Byron, Peter R. et al., *Drug Carrier Selection - Important Physicochemical Characteristics* RESPIRATORY DRUG DELIVERY, 5th Edition, Interpharm Press, 103-113 (1996)
	C38	Byström et al., "Microcalorimetry - A Novel Technique for Characterization of Powders", *Respiratory Drug Delivery IV*, 297-302 (1994)
	C39	Carpenter, John F. et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice", *Pharmaceutical Res.* 14:8:969-975 (1997)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C40	Casselyn, M. et al., *Time-Resolved Scattering Investigations of Brome Mosaic Virus Microcrystals Appearance* D58 ACTH CRYST. 1568-1570 (2002)
	C41	Caughey et al., "Sulphated Polyanion Inhibition of Scrapie-Associated PrP Accumulation in Cultured Cells", *J. Virol.* 67(2): 643-650 (1993)
	C42	Cevc, G., "Membrane Electrostatics" *Biochim. Biophy. Acta.*, 1031(3):311-382 (1990)
	C43	Chan et al., "Formulation of Vaccine Ajuvant Muramyldipeptides (MDP). 1. Characterization of Amorphous and Crystalline Forms of a Muramyldipeptide Analogue", *Pharmaceutical Research* 5(8): 523-527 (1988)
	C44	Chan, Hak-Kim et al, "Solid State Characterization of Spray-Dried Powders of Recombinant Human Deoxyribonuclease (RhDNase)", *Journal of Pharmaceutical Sciences*, 87(5):647-654 (1998)
	C45	Chan, Hak-Kim et al., "Physical Stability of Salmon Calcitonin Spray-Dried Powders for Inhalation" *Journal of Pharmaceutical Sciences* 93(3): 792-804 (2004)
	C46	Chavan, V. et al., "Effect of Rise in Simulated Inspiratory Flow Rate and Carrier Particle Size on Powder Emptying From Dry Powder Inhalers", *AAPS Pharmsci 2000*; 2(2) article 10 [on-line] Retrieved from the Internet < URL: http://www.pharmsci.org > 7 pages (2000)
	C47	Chavan, V. et al., "Novel System to Investigate the Effects of Inhaled Volume and Rates of Rise in Simulated Inspiratory Air Flow on Fine Particle Output From a Dry Powder Inhaler", *AAPS Pharmasci 2002*; 4(2) article 6 [on-line] Retrieved from the Internet < URL: http://www.aapspharmsci.org > 6 pages (2002)
	C48	Chavan, V. S. et al., "Effect of Particle Size and Rise in Simulated Inspiratory Flow Rate on Device Emptying in a Dry Powder Inhaler System", [on-line] [retrieved 01/07/2005] Retrieved from the Internet <URL: htpp://www.aapspharmsci.org/abstracts/AM_1999/1001.htm > 1 page (1999)
	C49	Chawla et al, "Production of Spray Dried Salbutamol Sulphate for Use in Dry Powder Aerosol Formulation", *International Journal of Pharmaceutics* 108: 233-240 (1994)
	C50	Chiou et al., "Pharmaceutical Applications of Solid Dispersion Systems", *J. Pharm.* 60(9): 1281-1302 (1971)
	C51	Cleland et al, "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation and Oxidation", *Critical Reviews in Therapeutic Drug Carrier Systems* 10(4): 307-377 (1993)
	C52	Cline, D. et al., "Predicting the Quality of Powders for Inhalation From Surface Energy and Area", *Pharmaceutical Research* 19(9):1274-1277 (2002)
	C53	Cline, D. et al., "Predicting the Quality of Powders for Inhalation", *Respiratory Drug Delivery VIII* 683-685 (2002)
	C54	Colaco et al., "Extraordinary Stability of Enzymes Dried in Trehalose: Simplified Molecular Biology," *Bio/Technology* 10: 1007-1011 (1992)
	C55	Colaco et al., "Trehalose Stabilization of Biological Molecules", *Biotechnol. Internat.*, pp. 345, 347-350 (1992)
	C56	Colaco et al., "Chapter 14: Chemistry of Protein Stabilization by Trehalose", *ACS Symposium Series 567, Formulation and Delivery of Proteins and Peptides*, J.L. Cleland & R. Langer, pp. 222-240 (1994)
	C57	Considine, G. D. et al, Van Nostrand's Scientific Encyclopedia, 9th edition, Volume 2, Wiley-Interscience, John Wiley & Sons, Inc., Definition of Vaccines: pp. 3591-3592 (2002)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C58	Costantino et al., "Moisture-Induced Aggregation of Lyophilized Insulin", *Pharmaceutical Research* 11(1): 21-29 (1994)
	C59	Costantino, H. R. et al., "Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody", *Journal of Pharmaceutical Sciences* 87(11):1406-1411 (1998)
	C60	Craig, I. D. et al., "Maillard Reaction Kinetics in Model Preservation Systems in the Vicinity of the Glass Transition: Experiment and Theory", *J. Agric. Food Chem.* 49(10):4706-4712 (2001)
	C61	Crommelin et al., "Liposomes", Chapter 3, *Colloidal Drug Delivery Systems,* J. Kreuter, editor: 73-190 (1994)
	C62	Crowe et al., "Are Freezing And Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes With Biomolecules", *Cryobiol.* 27:219-231 (1990)
	C63	Crowe et al., "Interactions of Sugars with Membranes", *Biochimica et Biophysica Acta* 947: 367-384 (1988)
	C64	Crowe, John H. et al., "The Role of Vitrification In Anhydrobiosis," *Annu. Rev. Physiol.* 60:73-103 (1998)
	C65	Crowe, Lois M. et al. "Is Trehalose Special for Preserving Dry Biomaterials?" *Biophysical Journal* 71:2087-2093 (1996)
	C66	D'Cruz, N. "Relationship Between Protein Thermal Stability and Glass Transition in Gelatin Polyol and Gelatin-Water Mixtures", PROCEEDINGS OF 2004 MEETING IFT, July 12-16, 2004, Las Vegas, NV, Session 17E, Food Chemistry: Proteins, [on-line] [retrieved 11/08/04] Retrieved from the Internet <URL: http://ift.confex.com/ift/2004/techprogram/paper_23006.htm > 17E-4 (2004)
	C67	D'Hondt, "Possible Approaches to Develop Vaccines Against Hepatitis A," *Vaccine* 10(Supplement 1): S48-S52 (1992)
	C68	Daemen et al., "The Destruction of Enzymes and Bacteria During the Spray-Drying of Milk and Whey, 2. The Effect of the Drying Conditions", *Neth. Milk Dairy J.* 36: 211-229 (1982)
	C69	Dalby, R. N. et al., "Droplets Drying and Electrostatic Collection a Novel Alternative to Conventional Comminution Techniques," *Journal of Biopharmaceutical Sciences* 3(1/2):091-099 (1992)
	C70	Dalby, R. N. et al., "Inhalation Therapy: Technological Milestones in Asthma Treatment", *Advanced Drug Delivery* 55: 779-791 (2003)
	C71	Dalby et al., "Relationship Between Particles Morphology and Drug Release Properties After Hydration of Aerosols Properties Containing Liposome Forming Ingredients", *Pharmaceutical Research* 5(10): S-94, Abstract PD 888 (1988)
	C72	Darrington et al., "Evidence for a Common Intermediate in Insulin Deamidation and Covalent Dimer Formation: Effects of pH and Aniline Trapping in Dilute Acidic Solutions", *Journal of Pharmaceutical Sciences* 84(3): 275-282 (1995)
	C73	De Carlo, S. et al., "Unexpected Property of Trehalose as Observed by Cryo-Electron Microscopy", *Journal of Microscopy* 196(1):40-45 (1999)
	C74	Dellamary et al., "Hollow Porous Particles in Metered Dose Inhalers", *Pharm. Research* 17(2): 168-174 (2000)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C75	Dose et al., "Survival in Extreme Dryness and DNA-Single-Strand Breaks," *Advances in Space Research*, 12(4): (4)221-(4)229 (1992)
	C76	During, M.J. et al., "Long-Term Behavioral Recovery in Parkinsonian Rats by an HSV Vector Expressing Tyrosine Hydroxylase," *Science* 266(5189):856-857 (November 1994)
	C77	Duzgunes et al., "Studies on the Mechanism of Membrane Fusion. Role of Head-Group Composition in Calcium- and Magnesium-Induced Fusion of Mixed Phospholipid Vesicles" *Biochim. Biophy. Acta.*, 642:184-195 (1981)
	C78	Ebara et al., "Interactions of Calcium Ions with Phospholipid Membranes" *Langmuir*, 10:2267-2271 (1994)
	C79	Edwards, A. D. et al. "Crystallization of Pure Anhydrous Polymorphs of Carbamazepine by Solution Enhanced Dispersion With Supercritical Fluids (SEDS™)", *Journal of Pharmaceutical Sciences* 90(8): 1115-1124 (2001)
	C80	Eisenberg et al., "Absorption of Monovalent Cations to Bilayer Membranes Containing Negative Phospholipids" *Biochem.*, 18(23):5213-5223 (1979)
	C81	Eleutherio et al., "Role of the Trehalose Carrier in Dehydration Resistence of Saccharomyces Cerevisiae," *Biochimica et Biophysica Acta* 1156: 263-266 (1993)
	C82	Elkordy et al., "Integrity of Crystalline Lysozyme Exceeds that of a Spray-Dried Form", *International Journal of Pharmaceutics* 247: 79-90 (2002)
	C83	Fahy et al., "Vitrification as an Approach to Cryopreservation", Cryobiology 21: 407-426 (1984)
	C84	Fakes, M. G. et al, "Moisture Sorption Behavior of Selected Bulking Agents Used in Lyophilized Products", PDA J. Pharm Sci. Technol. 54(2): 144-149, Abstract only [on-line] [retrieved 09/25/05] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov. > (2000)□
	C85	Finar, I. L. "§14. Trehalose, m.p. 203°C," under "Carbohydrate," Organic Chemistry, Volume 2, Stereochemistry and the Chemistry of Natural Products, 5th edition, Longman, page 323 (1996)
	C86	Forbes, R. T. et al., "Water Vapor Sorption Studies on the Physical Stability of a Series of Spray-Dried Protein/Sugar Powders for Inhalation", Journal of Pharmaceutical Sciences 87(11): 1316-1321 (1998)
	C87	Franks, "Freeze Drying: From Empiricism to Predictability," *Cryo-Letters* 11:93-110 (1990)
	C88	Franks, "Materials Science and the Production of Shelf-Stable Biologicals," *Pharmaceutical Technological International* 24:24-34 (October 1991)
	C89	Franks, "Separation, Improved Freeze-Drying, an Analysis of the Basic Scientific Principles", *Process Biochemistry* 24(1): iii-vii (1989)
	C90	Franks, "Accelerated Stability Testing of Bioproducts: Attractions and Pitfalls", *TIBTECH* 12:114-117 (1994)
	C91	Fukuoka et al., "Glassy State of Pharmaceuticals. V.Relaxation During Cooling and Heating of Glass by Differential Scanning Calorimetry", *Chem. Pharm. Bull.* 39(8): 2087-2090 (August 2001)
	C92	"Chapter 89-Oral Solid Dosage Forms," In *Remington's Pharmaceutical Science*, 18th Edition, Mack Publishing Co., Gennaro, A. R., pp. 1646-1647.
	C93	Goldbach et al., "Spray-Drying of Liposomes for a Pulmonary Administration I. Chemical Stability of Phospholipids", *Drug Develop Inc. Pharm.*, 19(19):2611-2622 (1993)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C94	Gordon et al., "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. I. Non-Crystalline Copolymers", *J. Appl. Chem.*, 2:493-500 (1952)
	C95	Green et al., "The Protein-Glass Analogy: Some Insights from Homopeptide Comparisons", *J. Phys. Chem.* 98:13780-13790 (April 1994)
	C96	Green et al., "Phase Relations and Vitrification in Saccharide-Water Solutions and the Trehalose Anomaly," *J. Phys. Chem.* 93:2880-2882 (1989)
	C97	Gupta, A. et al., "Single Virus Particle Mass Detection Using Microresonators with Nanoscale Thickness", *Applied Physics Letters* 84(11):1976-1978 (2004)
	C98	Hahn et al, "Solid Surfactant Solutions of Active Ingredients in Sugar Esters", *Pharmaceutical Research* 6: 958-959 (1989)
	C99	Hancock et al., "The Use of Solution Theories for Predicting Water Vapor Absorption by Amorphous Pharmaceutical Solids; A Test of the Flory-Huggins and Vrentas Models", *Pharmaceutical Research* 10(9): 1262-1267 (1993)
	C100	Hancock et al., "Molecular Mobility of Amorphous Pharmaceutical Solids Below Their Glass Transition Temperatures", *Pharmaceutical Research* 12(6): 799-806 (1995)
	C101	Hancock et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", *J. of Pharm. Sci.*, 86(1):1-12 (1997)
	C102	Hancock, B. C. et al., "The Effect of Temperature on Water Vapor Sorption by Some Amorphous Pharmaceutical Sugars", *Pharmaceutical Development and Technology* 4(1): 125-131 (1999)
	C103	Hancock, B. C. et al., "The Relationship Between the Glass Transition Temperature and Water Content of Amorphous Pharmaceutical Solids," *Pharmaceutical Research* 11(4):471-477 (1994)
	C104	Hancock et al., "A Pragmatic Test of Simple Calorimetric Method for Determining the Fragility of Some Amorphous Pharmaceutical Materials", Pharm Res. 15(5): 762-767 (1998)
	C105	Hanes et al., "Porous Dry-Powder PLGA Microspheres coated with Lung Surfactant for Systemic Insulin Delivery Via the Lung", *Proc. Int;l Symp. Control Rel. Bioactive Matter* 24:57-58 (1997)
	C106	Hatley, R. H. M. et al., "Stabilization of Labile Materials by Amorphous Carbohydrates Glass Fragility and the Physiochemical Properties that Make Trehalose a Superior Excipient", Pharmaceutical Research 13(9 Suppl.) PDD 7165: S274 (1996)
	C107	Hauser et al., "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers", *Biochim. Biophys. Acta.*, 813:343-346 (1985)
	C108	Hauser et al., "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" *Biochem.*, 23:34-41 (1984)
	C109	"Pfizer and Inhale Therapeutic Systems Enter Pulmonary Insulin Collaboration for Dry Powder Aerosol Delivery," Health News Daily, Volume 7, No. 13, pp. 4-5 (January 1995)
	C110	Heitefuss, R. et al. "The Stabilization of Extracts of Cabbage Leaf Proteins by Polyhydroxy Compounds for Electrophoretic and Immunological Studies," Archives of *Biochemistry and Biophysics* 85:200-208 (1959)
	C111	Heller, Martin C. et al., *Protein Formulation and Lyophilization Cycle Design: Prevention of Damage Due to Freeze-Concentration Induced Phase Separation* 63 BIOTECHNOLOGY & BIOENGINEERING 166-174 (1999)
	C112	Herrington, T. M. et al., "Physico-Chemical Studies on Sugar Glasses. I. Rates of Crystallization," *Journal of Food Technology* 19:409-425 (1984)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C113	Hickey, A. J. et al., "Behavior of Hygroscopic Pharmaceutical Aerosols and the Influence of Hydrophobic Additives," *Pharmaceutical Research* 10(1):1-7 (1993)
	C114	Hickey, A J. et al., "Methods of Aerosol Particle Size Characterization," *Pharmaceutical Inhalation Aerosol Technology* 8:219-253 (1992)
	C115	Hoener, Betty-Ann et al., "Factors Influencing Drug Absorption and Availability", Modern Pharmaceutics, Gilbert S. Banker et al., eds., Marcel Dekker Inc., Chapter 4, pp. 121-153 (1996)
	C116	Huster et al., "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction", *Biophys. J.*, 77(2):879-887 (1999)
	C117	Huster et al., "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" *Biophys. J.* 89(6): 3011-3018 (2000)
	C118	Ibrahim, A. L. et al., "Spray Vaccination With an Improved F Newcastle Disease Vaccine. A Comparison of Efficacy With the B1 and La Sota Vaccines," *Br. Vet. J.* 139:213-219 (1983)
	C119	Igaki, N. et al "The Inhibition of the Maillard Reaction by L Lysine In-Vitro," *J. Jpn. Diabetes Soc.* 34(5):403-407 (1991) including English abstract
	C120	Iglesias et al., "Adsorption Isotherm of Amorphous Trehalose", *J. Sci. food Agric.* 75:183-186 (1997)
	C121	Jacobson et al. "Phase Transitions and Phase Separations in Phospholipid Membranes Induced by Changes in Temperature, pH, and Concentration of Bivalent Cations" *Biochem.* 14(1):152-161 (1975)
	C122	Jameel, F. et al., "Freeze Drying Properties of Some Oligonucleotides", *Pharmaceutical Development and Technology* 6(2):151-157 (2001)
	C123	Jovanovic-Peterson, L. et al "Jet-injected insulin is associated with decreased antibody production and postprandial glucose variability when compared with needle-injected insulin in gestational diabetic women," *Diabetes Care* 16(11):1479-1484 (November 1993)
	C124	Kachura, "Method of Drying Lactic Acid Bacteria," Vinodelie I Vinogradarstvo SSSR 2:49-50, English Abtract only, one page (1985)
	C125	Kanna, K. et al. "Denaturation of Fish Muscle Protein by Dehydration" *Bull. Tokai Reg. Fish. Res. Lab.* 77:70-76 English abstract (1974)
	C126	Karmas, R. et al., "Effect of Glass Transition on Rates of Nonenzymatic Browning in Food Systems," *J. Agric. Food Chem.* 40:873-879 (1992)
	C127	Khan, R. "Chemistry And New Uses Of Sucrose: How Important?" *Pure & Appl. Chem.* 56(7):833-844 (1984)
	C128	Khan, R "Cyclic Acetals Of 4,1',6'-Tricholoro-4,1',6'-Trideoxy-Galacto-Sucrose And Their Conversion Into Methyl Ether Derivatives," *Carb. Res.* 198:275-283 (1990)
	C129	Klein, T. M. et al., "High Velocity Microprojectiles For Delivering Nucleic Acids Into Living Cells," *Nature* 327:70-73 (1987)
	C130	Kwon et al., "Calcium Ion Adsorption on Phospholipid Bilayers-Theoretical Interpretation" *J. Jap. Oil Chem Soc.* 43(1):23-30 (1994)
	C131	Labuza et al., "Glass Transition Temperatures of Food Systems", [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: http://faculty.che.umn.edu/fscn/Ted_Lebuza/PDF_files/Isotherm_Folder/Tg%20compilation.pdf > pp. 1-31 (January 1992)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C132	Labrude, P. et al., "Protective Effect of Sucrose on Spray Drying of Ocxyhemoglobin," *Journal of Pharmaceutical Sciences*, 78(3):223-229 (1989)
	C133	Lai, M. C. et al., "Solid-State Chemical Stability of Proteins and Peptides", *Journal of Pharmaceutical Sciences* 88(5):489-500 (1999)
	C134	Laube, B. L. et al., "Targeting Aerosol Deposition in Patients With Cystic Fibrosis, Effects of Alterations in Particle Size and Inspiratory Flow Rate", *Chest* 118(4): 1069-1076 (2000)
	C135	Ledl, F., et al., "New Aspects of the Maillard Reaction in Foods and in the Human Body," *Ang. Chem, Int. Ed.* Engl. 29:565-594 (June 1990)
	C136	Lee, C. K. Developments in Food Carbohydrate - 2nd edition Applied Science Publishers, London, Table of Contents, 4 pages (1980)
	C137	Lee, G., " Spray Drying of Proteins," Chapter 6, Rational Design of Stable Protein Formulations, Theory and Practice, J. F. Carpenter & M. Manning, pp. 135-158 (2002)
	C138	Lehninger, Albert L. *The Molecular Basis of Cell Structure and Function* BIOCHEMISTRY, Chapter 31, 859-890 (Worth Publishers Inc., 2nd edition, 1975)
	C139	Leslie, S. B. et al., "Trehalose and sucrose protect both membranes and proteins in intact bacteria during drying", *Appl. Env. Microbiol.* 61(10): 3592-3597 (1995)
	C140	Leuner, C. et al. "Improving Drug Solubility for Oral Delivery Using Solid Dispersions", *European Journal of Pharmaceutics and Biopharmaceutics* 50:47-60 (2000)
	C141	Levine et al., "Another View of Trehalose for Drying and Stabilizing Biological Materials," *Biopharm* 5:36-40 (1992)
	C142	Li, Z. et al., "Realistic In Vitro Assessment of Dry Powder Inhalers", *Respiratory Drug Delivery VIII*, pp. 687-689 (2002)
	C143	Lin, S.-Y. et al., "Solid Particles of Drug-β-Cyclodextrin Inclusion Complexes Directly Prepared by a Spray-Drying Technique", *International Journal of Pharmaceutics*, 56:249-259 (1989)
	C144	Lis et al., "Adsorption of Divalent Cations to a Variety of Phosphatidylcholine Bilayers", *Biochem.* 20:1771-1777 (1981)
	C145	Lis et al., "Binding of Divalent Cations to Dipalmitoylphosphatidylcholine and Its Effect on Bilayer Interaction", *Biochem.* 20:1761-1770 (1981)
	C146	Liu, Jinsong et at., "Dynamics of Pharmaceutical Amorphous Solids: The Study of Enthalpy Relaxation by Isothermal Microcalorimetry", *Journal of Pharmaceutical Sciences* 91(8):1853-1862 (2002)
	C147	Louey, M. D. et al., "Controlled Release Products for Respiratory Delivery", *APR*, 7(4):82-87 [on-line] [retrieved 09/2005] Retrieved from the Internet < URL: http://www.americanpharmaceuticalreview.com/article.aspx?article=77 > 11 pages (2004)
	C148	Louis, P. et al., "Survival Of Escherichia Coli During Drying And Storage In The Presence of Compatible Solutes" *Appl. Microbiol. Biotechnol.* 41:684-688 (1994)
	C149	Lueckel, B. et al., "Effects of Formulation and Process Variables on the Aggregation of Freeze-Dried Interleukin-6 (IL-6) After Lyophilization and on Storage", *Pharmaceutical Development and Technology* 3(3):337-346 (1998)
	C150	MacKenzie, "Collapse During Freeze Drying-Qualitative and Quantitative Aspects," *Freeze Drying and Advanced Food Technology*, edited by Goldblith, Rey and Rothmayr: 277-307 (1975)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C151	Makower, B. et al., "Equilibrium Moisture Content and Crystallization of Amorphous Sucrose and Glucose," *Agric. And Food Chem.* 4(1):72-77 (1956)
	C152	Martin, A. et at., *States of Matter and Phase Equilibria* PHYSICAL PHARMACY, PHYSICAL CHEMICAL PRINCIPLES IN THE PHARMACEUTICAL SCIENCES, 3rd. ed., Chapter 4, 62-92 (1983)
	C153	Masters, K. SPRAY DRYING HANDBOOK, England; Longman Scientific & Technical, 5th ed., pp. 640-642 (1991)
	C154	Masters, K. SPRAY DRYING HANDBOOK, England; Longman Scientific & Technical and John Wiley & Sons, Inc., 5th ed., pp. 309-352 (1991)
	C155	Masters, K *SPRAY DRYING HANDBOOK*, 5th ed., Chapters 13 and 15, pp. 491-537 and 587-642 (1991)
	C156	Matsuda, Y. et al., "Amorphism and Physicochemical Stability of Spray Dried Frusemide," *J. Pharm. Pharmacol.* 44:627-633, received November 7, 1991 (1992)
	C157	Mattern et al., "Formulation of Proteins in Vacuum-Dried Glasses. II. Process and Storage Stability in Sugar-Free Amino Acid Systems", Pharmaceutical Development &Technology 4(2):199-208 (1999)
	C158	Miller, D. P. et al., "Stabilization of Lactate Dehydrogenase Following Freeze-Thawing and Vacuum-Drying in the Presence of Trehalose and Borate", *Pharmaceutical Research* 15(8):1215-1221 (1998)
	C159	Millqvist-Fureby et al., "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures", *Int. J. Pharm.* 191:103-114 (1999)
	C160	Millqvist-Fureby et al., "Spray-Drying of Trypsin - Surface Characterization and Activity Preservation", *Int. J. Pharm.*, 188:243-253 (1999)
	C161	Molina, M. C. et al., "The Stability of Lyophilized Lipid/DNA Complexes During Prolonged Storage," *J. Pharm. Sci.* 93(9):2259-2273, abstract only, one page, [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: http://www.ncbi.nlm.nih.gov >, (2004)
	C162	Monnier et al., *Mechanisms of Protection Against Damage Mediated by the Maillard Reaction in Aging Gerontology* 37:152-165 (1991)
	C163	Mouradian, R. et al., "Degradation of Functional Integrity During Long-Term Storage of a Freeze-Dried Biological Membrane", *Cryobiology* 22: 119-127 (1985)
	C164	Moynihan et al., "Dependence of the Glass Transition Temperature on Heating and Cooling Rate", *J. Physical. Chem.* 78(26): 2673-2677 (1974)
	C165	Mumenthaler, M. et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," *Clinical Research* 11(1): 12-20 (1994)
	C166	Murphy, B. R. et al., "Chapter 19: Immunization Against Viruses", in Fields of Virology, 2nd Edition, Volume 1, Raven Press, pp. 469-502 (1990)
	C167	Murphy, Brian R. et al., Fields Virology, Volume 1, Chapter 16, *Immunization Against Virus Disease,* 467, at page 468, first full paragraph, first column, lines 26-33 (Bernard N. Fields et al. eds., Lippincott-Raven Publishers, 3rd ed. 1996)
	C168	Nabel, G. J. et al., "Direct Gene Transfer With DNA-Liposome Complexes in Melanoma," Proc. Natl. Acad. Sci. 90:11307-11311

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C169	Nabel, G. J. et al., "Immunotherapy of Malignancy by In Vivo Gene Transfer Into Tumors," *Hum. Gene. Ther.* 3(4): 399-410 (August 1992) Abstract only [on-line] [retrieved 112/21/04] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstr >
	C170	Naini, V. et al., "Particles for Inhalation Produced by Spray Drying and Electrostatic Precipitation of Different Protein-Sugar Solutions", *Respiratory Drug Delivery V*, pp. 382-384 (1996)
	C171	Naini, V. et al., "Physicochemical Stability of Crystalline Sugars and Their Spray-Dried Forms: Dependence Upon Relative Humidity and Suitability for Use in Powder Inhalers", *Drug Development and Industrial Pharmacy* 24(10):895-909 (1998)
	C172	Natarajan, P., Crystallization Conditions for VIPER Entries [on-line] [retrieved 11/04/04] Retrieved from the Internet <URL: http://www.xtal.tsinghua.edu.cn/research/groups/web/material/Virus%20Crystallization%2OPage.htm > 5 pages (last updated Jan. 3, 2002)
	C173	Niven, R. W. "Delivery of Biotherapeutics by Inhalation Aerosol," *Critical Reviews in Therapeutic Drug Carrier Systems*, 12(2&3):151-231 (1995)
	C174	Niven, R. W. "Delivery of Biotherapeutics by Inhalation Aerosols," *Pharmaceutical Technology* 72-75, 80 (July 1993)
	C175	Norberg, J. et al., "Glass Transition in DNA From Molecular Dynamics Simulation", *Proc. Natl. Acad. Sci. USA* 93:10173-10176 (1996)
	C176	Odegard, P. S. et al., "Inhaled Insulin: Exubera", *The Annals of Pharmacotherapy* 39:843-853 (2005)
	C177	Ohtake, S. et al., "Effect of pH, Counter Ion and Phosphate Concentration on the Glass Transition Temperature of Freeze-Dried Sugar-Phosphate Mixtures", *Pharmaceutica Research* 21(9):1615-1621 (2004)
	C178	Okamoto, H. et al., "Dry Powders for Pulmonary Delivery of Peptides and Proteins", *Kona* 20:71-83 (2002)
	C179	Oksanen et al., "The Relationship between the Glass Transition Temperature and Water Vapor Absorption by Poly(Vinylpyrrolidone)," *Pharmaceutical Research* 7(6): 654-657 and errata on page 974 (1990)
	C180	Okumura, K. et al., "Intratracheal Delivery of Calcitonin Dry Powder in Rats and Human Volunteers," *S.T.P. Pharmaceutical Sciences* 4(1):5 pages (January, February 1994)
	C181	Onodera et al., "Glass Transition of Dehydrated Amorphous Solid", *Bull. Chem. Soc. Japan* 41(9): 2222 (1968)
	C182	Owens, D. R. et al., "Alternative Routes of Insulin Delivery," *Diabetic Medicine* 20:886-898 (2003)
	C183	Palmer, K. J. et al. "X-Ray Diffractometer and Microscopic Investigation of Crystallization of Amorphous Sucrose," Agricultural and Food Chemistry 4(1): 77-81 (January 1956)
	C184	Parasassi et al., "Calcium-Induced Phase Separation in Phospholipid Bilayers. A Fluorescence Anisotropy", *Cellular and Molecul. Bio.*, 32(3):261-266 (1986)
	C185	Parks, "Studies on Glass. II The Transition Between the Glassy and Liquid States in the Case of Glucose", *Journal of Physical Chemistry* 1366-1379 (1928)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C186	Patel, M. M. et al., "Degradation Kinetics of High Molecular Weight Poly(L Lactide) Microspheres and Release Mechanism of Lipid: DNA Complexes", *Journal of Pharmaceutical Sciences*, 93(10): 2573-2584 (2004)
	C187	Pearlman et al., "Formulation Strategies for Recombinant Proteins: Human Growth Hormone and Tissue Plasminogen Activator", Therapeutic Peptides and Proteins, Formulation, Delivery and Targeting, Cold Spring Harbour, New York, pp. 23-30 (1989)
	C188	Pekarek et al., "Double-walled polymer microspheres for controlled drug release," *Nature* 367:258-260 (1994)
	C189	Phillips, E. et al., "Size Reduction of Peptides and Proteins by Jet-Milling", *Respiratory Drug Delivery VI*, pp. 161-167 (1998)
	C190	Pikal, M. J., "Freeze-Drying of Proteins Part II: Formulation Selections," *Biopharm* 3(8):26-30 (October 1990)
	C191	Pikal, M. J. et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form", *Pharmaceutical Research* 14(10):1379-1387 (1997)
	C192	Pikal et al., "Thermal Decomposition of Amorphous β-Lactam Antibacterials", *Journal of Pharmaceutical Science* 66(9): 1312-1316 (September 1977)
	C193	Pikal, M. J. et al., Errata of "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," *Pharmaceutical Research* 15(2):362-363 (1998)
	C194	Pine, S. H. et al., "15-3 Oligosaccharides and Polysaccharides," *Organic Chemistry*, 4a' edition, McGraw-Hill International Book Company, page 763 (1980)
	C195	Pisecky, J. "2. Evaporation and Membrane Filtration", Handbook of Milk Powder Manufacture, Niro A/S, Denmark, page 3 (1997)
	C196	Pocchiari, M. et al. "Amphotericin B: A Novel Class of Antiscrapie Drugs," *J. Infect. Dis.* 160(5):795-802 (November 1989)
	C197	Prestrelski, S. J. et al., "Optimization of Lyophilization Conditions for Recombinant Human Interleukin-2 by Dried-State Conformational Analysis Using Fourier-Transform Infrared Spectroscopy," *Pharmaceutical Research* 12(9):1250-1259 (1995)
	C198	Prestrelski, S. J. et al., "Separation of Freezing- and Drying-Induced Denaturation of Lyophilized Proteins Using Stress-Specific Stabilization," *Archives of Biochemistry and Biophysics* 303(2):465-473 (June 1993)
	C199	Quan, C. *Protein Science* 4(2):148, Abstract No. 490-T (1995)
	C200	Ramanujam, R. et al., "Ambient-Temperature-Stable Molecular Biology Reagents," *Biotechniques* 14(3):470-473 (1993)
	C201	Reboiras, M.D., "Activity Coefficients of $CaCl_2$ in the Presence of Dipalmitoylphosphatidylcholine-Phosphatidylinositol Vesicles in Aqueous Media", *Bioelectrochemistry and Bioenergetics*, 39:101-108 (1996)
	C202	Ringe, D. et al., "The `Glass Transition in Protein Dynamics: What it is, Why it Occurs, and How to Exploit It", *Biophys. Chem.* 105(2-3):667-680, Abstract only, [on-line] [retrieved 11/19/04] Retrieved from the Internet < URL: http://www.ncbi.nlm.nih.gov > (2003)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C203	Roos, "Phase Transitions of Mixtures of Amorphous Polysaccharides and Sugars," *Biotechnology Progress* 7(1): 49-53 (1991)
	C204	Roser et al. "A Sweeter Way To Fresher Food" *New Scientist* pp. 25-28 (May 15, 1993)
	C205	Roser, B. "Trehalose, A New Approach To Premium Dried Foods," *Trends in Food Sci. and Tech.* pp. 166-169 (July 1991)
	C206	Roser, B. "Trehalose Drying: A Novel Replacement For Freeze Drying" *Biopharm* 4:47-53 (1991)
	C207	Roth et al., "Production of Hollow Spheres", *Paragamon Press*, Vol. 19, No. 7, pp. 939-942 (1998)
	C208	Royall et al., "Characterisation of Mixture Uptake Effects on the Glass Transitional Behaviour of an Amorphous Drug Using Modulate Temperature DSC", *Int. J. Pharm.*, 192:39-46 (1999)
	C209	Saleki-Gerhardt, A. et al., "Non-Isothermal and Isothermal Crystallization of Sucrose From the Amorphous State," *Pharmaceutical Research* 11(8):1166-1173 (1994)
	C210	Saleki-Gerhardt, A. et al., "Hydration and Dehydration of Crystalline and Amorphous Forms of Raffinose," *Journal of Pharmaceutical Sciences*, 84(3):318-323 (March 1995)
	C211	Sambrook, et al., Molecular Cloning: A Laboratory Manual, 2nd. ed., "CONCENTRATING NUCLEIC ACIDS: Precipitation with Ethynol or Isopropanol", pp. E.10-E.17, Cold Spring Harbor Laboratory Press (1989)
	C212	Sanchez, J. et al., "Recombinant System for Overexpression of Cholera Toxin B Subunit In Vibrio Cholerae as a Basis for Vaccine Development" *Proc. Natl. Acad. Sci.* USA 86:481-485 (1989)
	C213	Sarkar and Moore, "Immunization of Mice Against Murine Mammary Tumor Virus Infection and Mammary Tumor Development," *Cancer Research* 38: 1468-1472 (1978)
	C214	Satoh, Koichi, "Determination of Binding Constants of Ca2+, Na+, and Cl- Ions to Liposomal Membranes of Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis", *Biochem. Biophys. Acta* 1239:239-248 (1995)
	C215	Schamblin and Zografi, "Enthalpy Relaxation in Binary Amorphous Mixtures Containing Sucrose", *Pharmaceutical Research* 15(12): 1828-1834 (December 1998)
	C216	Schebor, C. et al., "Color Formation Due to Non-Enzymatic Browning in Amorphous, Glassy, Anhydrous, Model Systems", *Food Chemistry* 65:427-432 (1999)
	C217	Sciarra et al., "Aerosols", *Remington's Pharmaceutical Sciences,* Chap. 93, 17th Ed., Mack Publishing Company, Alfonso R. Gennaro, editor, pp. 1662-1677 (1985)
	C218	Sebhatu, T. et al., "Assessment of the Degree of Disorder in Crystalline Solids by Isothermal Microcalorimetry," *International Journal of Pharmaceutics* 104:135-144 (1994)
	C219	Seddon, J.M., "Structure of the Inverted Hexagonal (H11) Phase, and Non-Lamellar Phase Transitions of Lipids", *Biochem Biophys. Acta.*, 1031:1-69, in particular pp. 43-44 and 49-50 (1990)
	C220	Seelig, Joachim, "Handbook Met. - Ligand Interact. Biol. Fluids, Bioinorg. Chem., Section, Metal Ion Interaction with Lipids" pp. 698-706 (1995)
	C221	Sellers, S. P. et al., "Dry Powders of Stable Protein Formulations From Aqueous Solutions Prepared Using Supercritical C02-Assisted Aerosolization", *Journal of Pharmaceutical Sciences* 90(6):785-797 (2001)
	C222	Serajuddin, A. T. M. et al., "Effect of Thermal History on the Glassy State of Indapamide," *J. Pharm. Pharmacol.* 38:219-220 (1986)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C223	Shah et al., "The Ionic Structure of Sphingomyelin Monolayers", *Biochem Biophys. Acta.*, 135:184-187 (1967)
	C224	Shalaev, E. Y. et al., "How Does Residual Water Affect The Solid-State Degradation of Drugs in the Amorphous State", *Journal of Pharmaceutical Sciences*, 85(11):1137-1141 (1996)
	C225	Shalaev, E.Y. et al., "Structural Glass Transitions and Thermophysical Processes in Amorphous Carbohydrates and Their Supersaturated Solutions," *J. Chem. Soc. Faraday Trans.* 91(10):1511-1517 (1995)
	C226	Sharma, V. K. et al., "Effect of Vaccum Drying on Protein-Mannitol Interactions: The Physical State of Mannitol and Protein Structure in the Dried State," AAPS PharmSciTech 5(1) Article 10:1-12 [on-line] [retrieved] Retrieved from the Internet <URL: http://www.aapspharmscitech.org > (2004)
	C227	Shavnin et al., "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" *Biochem Biophys Acta.*, 946:405-416 (1988)
	C228	Simha et al., "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers", *J. Chem. Physics*, 37(5):1003-1007 (1962)
	C229	Singer et al"Thermotolerance in Saccharomyces Cerevisiae: the Yin and Yang of Trehalose", *Tibtech* 16:460-468 (1998)
	C230	Skrabanja et al., "Lyophilization of Biotechnology Products" *PDA J. Pharm. Sci. Technol.* 48(6):311-317 (1994)
	C231	Slade and Levine, "The Glassy State Phenomenon in Food Molecules," *The Glassy State in Foods*, Blanshard & Lillford, editors: 35-101 (1993)
	C232	Slade and Levine, "Non-Equilibrium Behavior of Small Carbohydrate-Water Systems," *Pure and Applied Chemistry*, 60(12): 1841-1864 (1988)
	C233	Sokolov et al., "Glassy Dynamics in DNA: Ruled by Water of Hydration" *Journal of Chemical Physics* 110(14):7053-7057 (1999)
	C234	Sola-Penna, Mauro et al., *Stabilization Against Thermal Inactivation Promoted by Sugars on Enzyme Structure and Function: Why is Trehalose More Effective Than Other Sugars?* 360(1) ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS 10-14, Article No. BB9809606, (December 1998)
	C235	Sonner, C. et al., "Spray-Freeze-Drying for Protein Powder Preparation: Particle Characterization and a Case Study With Trypsinogen Stability", *Journal of Pharmaceutical Sciences* 91(10):2122-2139 (2002)
	C236	Spi Polyols™ "What are Polyols? What do Polyols do? What are Polyols' functionality?", [on-line] [retrieved 06/25/04] Retrieved from the Internet <URL: http://www.spipolyols.com/whatarepolyols.html > one page (2003)
	C237	Stribling, R. et al., "Aerosol Gene Delivery in Vivo," *Proc. Natl. Acad. Sci.* 89:11277-11281 (December 1992)
	C238	Strickley, R. G. et al., "Solid-State Stability of Human Insulin II. Effect of Water on Reactive Intermediate Partitioning in Lyophiles from pH 2-5 Solutions: Stabilization Against Covalent Dimer Formation", *Journal of Pharmaceutical Sciences* 86(6):645-653 (1997)
	C239	Strom, A. R. and Kaasen, I., "Trehalose Metabolism in Escherichia coli: Stress Protection and Stress Regulation of Gene Expression", *Molecular Microbiology* 8(2):205-210 (1993)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C240	Stubberud, L. et al., "The Use of Gravimetry For The Study of the Effect of Additives on the Moisture-Induced Recrystallisation of Amorphous State", *International Journal of Pharmaceutics* 163:145-156 (1998)
	C241	Sugisaki et al., "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice", *Bulletin of the Chem. Soc. Of Japan*, 41:2591-2599 (1968)
	C242	Sukenik et al., "Enhancement of a Chemical Reaction Rate by Proper Orientation of Reacting Molecules in the Solid State", *J. Am. Chem. Soc.* 97: 5290-5291 (September 1975)
	C243	Sussich, F. et al., "Reversible Dehydration of Trehalose and Anhydrobiosis: From Solution State to an Exotic Crystal?", *Carbohydrate Research* 334:165-176 (2001)
	C244	Takahashi et al., "Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs", *Nature* 344:873-875 (April 1990)
	C245	Tarelli, E. et al., "Additives to Biological Substances. III. The Moisture Content and Moisture Uptake of Commonly Used Carrier Agents Undergoing Processing Conditions Similar to Those Used in the Preparation of International Biological Standards," *Journal of Biological Standardization* 15:331-340 (1987)
	C246	Tatulian, S.A., "Binding of Alkaline-Earth Metal Cations and Some Anions to Phosphatidylcholine Liposomes", *Eur. J. Biochem.*, 170:413-420 (1987)
	C247	Tatulian, S.A., "Evaluation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration Dependence Surface Potential", *J. Colloid Interface Science*, 175:131-137 (1995)
	C248	Thatcher, E., "Quantitation of Virus" [on-line] [retrieved 11/01/04] Retrieved from the Internet <URL: http://www.sonoma.edu/users/t/thatcher/bio1383/lab.htm > 4 pages, (last updated Jan. 5, 2002)
	C249	Timko et al. "Thermal Analysis Studies of Glass Dispersion Systems", *Drug Devel. Ind. Pharm.* 10:425-451 (1984)
	C250	Timsina, T. et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," *International Journal of Pharmaceutics* 101:1-13 (1994)
	C251	To et al., "Collapse, a Structural Transition in Freeze Dried Carbohydrates", *J. Fd. Technol.* 13: 567-581 (1978)
	C252	Toyama, A. (ed) Handbook of Natural Product for food processing, 9th Edition, Osaka, Japan, Shokuhin to Kagaku Sha, pages 384 and 495 (ISBN4-87994-048-8), (1986)
	C253	Tsourouflis, S. et al., "Loss of Structure in Freeze-Dried Carbohydrates Solutions: Effect of Temperature, Moisture Content and Composition," *J. Sci. Fd. Agric.* 27:509-519 (1976)
	C254	Ulrich, "Biophysical Aspects of Using Liposomes as Delivery Vehicles", *Bioscience Reports* 22(2):129-150 (2002)
	C255	Underwood et al., "A Novel Technique for the Administration of Bronchodilator Drugs Formulated as Dry Powders to the Anaesthetized Guinea Pig", *J. of Pharmacological Methods*, Vol. 26, pp. 203-210, 1991
	C256	Uritani, M. et al., "Protective Effect of Disaccharides on Restriction Endonucleases During Drying Under Vacuum," *J. Biochem.* 117:774-779 (1995)
	C257	Vain et al., "Development of the particle inflow gun", *Plant Cell, Tissue and Organ Culture* 33:237-246 (1993)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C258	Vavelyuk, O.L. et al., "Thermostability of DNA and Its Association with Vitrification", *Tsitologiya* 41(11):958-965 (1999)
	C259	Verstraeten et al., "Effects of A1(3+) and Related Metals on Membrane Phase State and Hydration: Correlation with Lipid Oxidation", *Arch. Biochem. Biophys.*, 375(2):340-346 (2000)
	C260	Vidgrén, M. T. et al., "Comparison of Physical and Inhalation Properties of Spray-Dried and Mechanically Micronized Disodium Cromoglycate," *International Journal of Pharmaceutics* 35:139-144 (1987)
	C261	Vromans, H. et al., "Studies on Tableting Properties of Lactose. VII. The Effect of Variations in Primary Particle Size and Percentage of Amorphous Lactose in Spray Dried Lactose Products," *International Journal of Pharmaceutics* 35:29-36 (1987)
	C262	Wang, et al. eds. Stability and characterization of protein and peptide drugs, Table of Contents, 6 pages (1993)
	C263	Welsh, D. T., "The Role of Compatible Solutes In the Adaptation and Survival of Escherichia coli," Ph.D. Thesis Submitted to Department of Biological Sciences, University of Dundee. pp. 1-262 . (August 1992)
	C264	Whipps et al., "Growth of Calcium Monohydrate at Phospholipid Langmuir Monolayers"., *J. Cryst. Growth*, 192:243-249 (1998)
	C265	Whittier, E., "Lactose and its Utilization: A Review," *J. Dairy Sci.* 27(7)505-537 (July 1994)
	C266	William and Leopold, "The Glassy State in Corn Embryos" Plant Physiology 89:977-981 (1979)
	C267	Williams et al., "The Temperature Dependence of Relaxation Mechanisms in Amorphous Polymers and Other Glass Forming Liquids", *The Journal of the American Chemical Society* 77: 3701-3707 (1955)
	C268	Wolff, J. A. et al., "Grafting Fibroblasts Genetically Modified to Produce L-Dopa in a Rat Model of Parkinson Disease," *Proc. Natl. Acad. Sci.* 86:9011-9014 (November 1989)
	C269	Xi, Y. G. et al., "Amphotericin B Treatment Dissociates in Vivo Replication of the Scrapie Agent From PrP Acummulation", *Nature* 356:598-601 (April 1992)
	C270	Yamaguchi et al., "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" *Colloids and Surface B: Biointerfaces*, 5:49-55 (1995)
	C271	York, "Powdered Raw Materials: Characterizing Batch Uniformity," *Respiratory Drug Delivery IV, Programs and Proceedings*, edited by Byron, Dalby and Farr: 83-91 (1994)
	C272	Yoshida, H. et al., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form," *Journal of Pharmaceutical Sciences* 68(5): 670-671 (May 1979)
	C273	Yoshinari, T. et al., "Moisture Induced Polymorphic Transition of Mannitol and its Morphological Transformation", *International Journal of Pharmaceutics*, 247:69-77 (2002)
	C274	Yoshioka, M. et al., "Crystallisation of Indomethacin From the Amorphous State Below and Above Its Glass Transition Membrane," *Journal of Pharmaceutical Sciences* 83(12):1700-1705 (December 1994)
	C275	Zarif et al., "Amphotericin B Cochleates as a Novel Oral Delivery System for the Treatment of Fungal Infections", Proceedings of the International Symp. on Controlled Release Bioactive Materials., pp. 964-965 (1999)
	C276	Zubay, G. BIOCHEMISTRY, SECOND EDITION, pages 39 & 169, Table 5-6 Major Steroid Hormones (1988)

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	C277	Zubay, G. BIOCHEMISTRY, SECOND EDITION, pages 216-232 "Structural Properties of DNA" (1988)
	C278	Nektar U.S. Patent Application No. 08/044,358, "Compositions and Methods For Nucleic Acid Delivery To The Lung" filed by Patton et al. on April 7, 1993, assigned to Inhale Therapeutic Systems.
	C279	Nektar U.S. Patent Application No. 08/422,563, filed April 14, 1995, Paper No. 17, Office communication mailed April 3, 1998 (Patent No. 5,994,314)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	